iCH Prime

CPAP System

Instruction Manual

Model No.: 9S-007100

Please read the instruction manual before use.

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IMPORTANT SAFEGUARDS
SAVE THESE INSTRUCTIONS
READ ALL INSTRUCTIONS BEFORE USING

WARNING –

1. THIS DEVICE IS NOT INTENDED FOR LIFE SUPPORT. It may stop operating due to power interruption without hazard to patient.
2. If oxygen is used with the device, the oxygen flow must be turned off when the device is not in use. **Explanation of the Warning:** When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device and create a risk of fire.
3. Oxygen is inflammable. Oxygen **should not** be used while smoking or in the presence of an open flame.
4. Always ensure the device is generating airflow before the oxygen supply is turned on. Always turn off the oxygen supply before stopping the airflow from the device.
5. This device **should not** be used in the vicinity of a flammable anaesthetic mixture in combination with oxygen or air and nitrous oxide.

⚠ **NOTE :** L'équipment ne peut être utilisé s'il y a risque de mélange d'un anesthésique inflammable avec l'air ou l'oxygène ou oxyde nitreux.

6. The airflow for breathing generated by this device may be as much as 7°C (12.6°F) higher than the room temperature. This device **should not** be used if the room temperature is warmer than 35°C (95°F) to prevent the airflow temperature from exceeding 40°C (104°F) and causing irritation to your airway.
7. If this device overheats, it will stop operating and show message “Error 002” on the display. After cooling down to the proper temperature, the device can be restarted.
8. This machine should be used only with masks (and connectors) recommended by the manufacturer, or by your doctor or respiratory therapist. A mask should not be used unless the CPAP machine is turned on and operating properly. The vent holes for the mask should never be blocked, to allow for proper exhaling. If the vent hole is blocked, the CPAP machine will stop and show message “**Error 002**”. After the machine cools down, please re-connect the power cord to reset the machine.
9. At low CPAP pressure, some exhaled gas may remain in the mask and bebreathed in again.

CAUTION –

1. Make sure the area around the machine is dry and clean. Dust and foreign particles may affect the treatment. Keep the air inlet on the back of the machine clear to prevent overheating and damage of the device. Do not place the machine near a source of hot or cold air. An extremely cold or hot environment may damage the user's respiratory airway.
2. If there is a possibility of electro-magnetic interference with mobile phones, please increase the distance between devices or turn off the mobile phone.
3. Do not connect the device to the personal computer for data downloading during the treatment. This may cause a failure in the CPAP system.
4. To prevent from potential allergic reactions to mask used in the device, This machine shall be used only with masks (and connectors) recommended by the manufacturer.
5. U.S. Federal law restricts this device to sale by or on the order of a licensed doctor.

DANGER -To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.
6. If product falls into water or other liquids do not reach into the water or other liquids. Unplug immediately.

WARNING -To reduce the risk of burns, electrocution, fire or injury to persons:

1. This product should never be left unattended when plugged in.
2. Close supervision is necessary when this product is used with or near children or invalids. Choking resulting from a child swallowing a small part that has become detached from the device or its accessories.
3. Use this product only for its intended use as described in this manual, do not use attachments not recommended by the manufacturer.
4. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service centre for examination and repair.
5. Keep the cord away from heated surfaces.
6. Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where the air openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
7. Never drop or insert any object into any opening or hose.
8. Follow the national requirementfor disposing of the unit.
9. Do not operate the device before the mask and water chamber have been installed.
10. Disconnect the water chamber from the device when not in use, water entering the device may result in electric shock hazard or damage.
11. Do not use if water comes in contact with the device or enters the tubing.
12. This device is not for use with patients whose supraglottic airways have been bypassed.
13. Do not cover the device with blankets or clothes .
14. Do not remove water chamber while humidifier is heating. Do not touch the heater plate for 30 minutes after the device is disconnected from the mains.
15. No modification of this equipment is allowed.
16. Do not modify this equipment without authorization of the manufacturer.
17. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.
18. Do not leave long lengths of air tubing around the top of your bed. It could twist around your head or neck while you are sleeping and lead to strangulation.

1. Introduction

This manual should be used for initial set up of the system and saved for reference purpose.

1.1 General Information

Obstructive Sleep Apnea (OSA) is a condition that an intermitted and repetitive obstruction of the upper respiratory tract causes a complete (apnea) or partial (hypopnea) block of breathing airflow during sleep. The syndrome varies depending on the degree of relaxation of the tongue and soft palate muscle.

The most common treatment for OSA is Continuous Positive Airway Pressure (CPAP). CPAP devices can deliver a constant air pressure into your upper airway via a nasal mask. This constant air pressure can keep your airway open during sleep, therefore prevents the OSA.

This device is a micro-processor controlled continuous positive airway pressure device. It features the illuminated, menu-driven LCD display, universal power supply and ramp time adjustment. The ramp time adjustment and ultra quiet operation ensure you to fall asleep comfortably while air pressure slowly builds up to treatment level. The user compliance meter records the total system's operating time for physician's reference.

The system has been tested and successfully approved to the following standards:

CE 0197	EN 60601-1 EN 60601-1-2 EN 61000-3-2 Class A EN 61000-3-3

For US and CANADA only

E348970
53DG

Medical Equipment- CPAP with integrated heated humidifier

WITH RESPECT TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES60601-1 (2005,3rd ed.) and CAN / CSA C22.2 No. 60601-1 (2008, 3rd ed.) and IEC 60601-1-11

Le produit à été testé avec des équipements médicaux et respecte les normes UL 60601-1 & CAN/CSA C22.2 No.601.1. prévenant les choc électrique, le feu et les risques de blessures physiques.

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the other device(s) are
  connected.
- Consult the manufacturer or field service technician for help.

This system has been tested for compliance to the following volunteer standards:
FDA

1.2 Intended Use

This device is intended to provide continuous positive airway pressure (CPAP) for the treatment of adult Obstructive Sleep Apnea (OSA). The integrated heated humidifier is designed to increase the humidity of the air from the CPAP thereby relieving the symptoms of a dry nose and throat that some people may experience.

⚠ **Cautions: Some patients might have pre-existing contraindications for CPAP therapy, or might experience some potential side effects of using a CPAP device. Please consult your doctor if you have any questions concerning your therapy.**

⚠ **NOTE: Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.**

2. Product Description

2.1 Unpacking the Contents

Components include:

(1) Main CPAP device with integrated heated humidifier
(2) Power supply adapter and AC power cord
(3) User manual
(4) Flexible air tubing, 1.8 m length
(5) Carrying bag
(6) SD card and USB cable

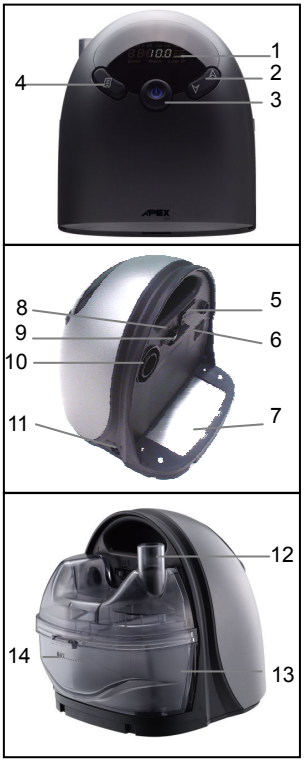
NOTE: Please use a SD card (smaller than 2GB) which complies with SDHC standard. Before using it, please format it to FAT16 to ensure correct data collection.

CAUTION: Patient should not connect the device to a personal computer for data downloading. This may cause the CPAP system failure.

To secure contents inside, the device and accessories are bundled in a paper packaged box. Unpack this box by removing the device and accessories and check for any damage, which may have occurred during shipping. If there are damages, please contact your dealer immediately.

2.2 System Overview

1. LCD Display
2. Up & Down Button
3. Start/Standby Button
4. Menu Button
5. SD Card Slot/mini-USB Connector
6. Air Filter
7. Heater Platform
8. Heater Indicator
9. Heater Control knob
10. Air Outlet
11. Power Socket
12. Air Outlet of the Water Chamber
13. Fill Line
14. Water Chamber



3. Installation

3.1 Disassembling the Water Chamber

1. Turn the device off and allow the heater and water to cool. If necessary, disconnect the flexible tubing from the water chamber.
2. Place thumb on the top of the water chamber and tip it upward as shown in Figure 3-1. Remove the water chamber from the system.
3. Unlock the water chamber by pulling the tab as shown in Figure 3-2. Remove the chamber lid from the base.

Figure 3-1

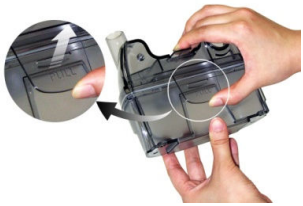


Figure 3-2

3.2 Filling the Water Chamber

1. Fill the chamber to the fill line with distilled water (approx. 300 ml), as shown in Figure 3-3.
2. If the silicon gasket has been removed, replace it securely on the top edge of the water chamber base. Otherwise, the device will not deliver air properly.
3. Position the water chamber on the heater plate and push the bottom forward to lock it in place, as shown in Figure 3-4. Make sure the silicon connector on the inlet connector fits securely over the CPAP device air outlet.

CAUTION: Do not overfill the water chamber. Damage to the device may occur.

CAUTION: Use only room temperature water; do not fill the chamber with hot or chilled water.

CAUTION: Do not turn the heater on without the water chamber installed

CAUTION: When installing the water chamber, do not allow water to spill into the device.

CAUTION: Do not move the device when the chamber has water in it.

Figure 3-3

Figure 3-4

3.3 Setting Up

1. Place the device on a flat surface and at a lower level than your sleeping position.
2. Connect one end of the air tubing firmly to the air outlet on the back of the device, as shown in Figure 3-5.
3. Connect the other end of the air tubing to the mask system. Put on the mask and headgear according to the mask instruction manual.
4. Plug the socket end of the AC power cord into the power supply adapter. Plug the pronged end of the AC power cord into a main electrical outlet.
5. Plug the power supply cord's adapter connector into the power inlet on the right side of the device, as shown in Figure 3-6.
6. Once the power supply cord's adapter connector is plugged into the power inlet, the CPAP system is in ready to operate position ("**STANDBY**" sign appears in LCD display)

⚠ **NOTE: The AC power cord also serves to disconnect the device.**

⚠ **NOTE: Do not position the equipment so that it is difficult to operate the disconnecting device.**

Figure 3-5

Figure 3-6

4. Operation

NOTE: Always read the operating instructions before use.

4.1 Control Panel Description

Buttons on control panel and main use of the buttons:

START/STANDBY

To start the treatment, simply press the ***"START/STANDBY"*** button. To stop the treatment, press the ***"START/STANDBY"*** button again. The display will switch between ***[STANDBY]*** and Therapy Pressure ***[XX.X cmH$_2$O]*** in cmH$_2$O unit.

MENU

Press the ***"MENU"*** button to enter the setting mode when device is in standby mode. The adjustment setting includes ramp time selection, ramp starting pressure, therapy pressure adjustment, alarm ON/OFF, clock alarm setting, compliance meter, and total operating meter. When each setting's value has been changed, press ***"MENU"*** for confirmation and press ***"MENU"*** again for next setting selection. Please refer to 4.3 Function Description section for detailed information.

UP

Press the ***"UP"*** button to increase the selected value.

DOWN

Press the ***"DOWN"*** button to decrease the selected value.

4.2 Function Description

Getting Started – First time use.

For first-time use, follow the steps below:

1. Make sure that your doctor or care provider has initialized and configured the appropriate treatment values into the unit.
2. Make sure that your package contains a face or nasal mask with headgear. If not, your doctor or care provider can recommend the type of mask and headgear you must obtain
3. Attach tubing and mask (see Setup section).
4. Attach power cord to the unit and an electrical outlet (see Setup section). Unit will power-on automatically.
5. Use the ***"MENU"*** button to set the Current Time, Ramp Up Time, and Ramp Starting Pressure, (see ***"MENU"*** Button Section for description of these options).
   Note that these values may have already been set by your doctor or care provider.
6. Press the ***"START/STANDBY"*** button – Airflow to the mask will begin.
7. You can now place the Headgear and Mask over your head and face and begin treatment.

4.3 Menu Button - Option Description

(1) Ramp Time (only CPAP mode)

Ramp time function allows user to fall into sleep with a lower, comfortable pressure and helps users gradually get accustomed to increasing treatment pressure. The first selection of pressing ***"MENU"*** is ***[Ramp XX MIN]***. When the ***"MENU"*** setting is in ***[Ramp XX MIN]*** mode, press ***"UP"*** or ***"DOWN"*** button to set the preferred ramp time and press ***"MENU"*** for confirmation. There are 10 adjustable levels, 0, 5, 10, 15, 20, 25, 30, 35, 40 and 45 minutes.

(2) Ramp Starting Pressure (only CPAP mode)

Press ***"MENU"*** button to select ***[Ramp P XX.X]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the preferred ramp starting pressure and press ***"MENU"*** for confirmation. The ramp starting pressure can be changed from 3 cmH_2O to "Therapy Pressure – 1" cmH_2O. For example, if your therapy pressure is 10 cmH_2O, the maximum ramp starting pressure you can select is 9 cmH_2O.

(3) Therapy Pressure (only CPAP mode)

Press ***"MENU"*** button to select the ***[P XX.XcmH$_2$O]*** menu. You can view the current pressure setting displayed in cmH_2O unit. Therapy pressure is adjustable only by the provider, a respiratory therapist or doctor.

⚠**NOTE:** The therapy pressure is to only be prescribed by a physician.

(4) PVA (Pressure Variation Algorithm)

Press ***"MENU"*** button to select ***[c on/off]*** menu, you can view if the PVA function is enabled by the provider, a respiratory therapist or physician. The PVA function delivers pressure relief upon exhalation to improve comfort. If the PVA function is enabled, press ***"UP"*** or ***"DOWN"*** button to adjust the comfort level. There are 3 adjustable levels of pressure relief that you feel while exhalation. Level 1 provides small pressure variation; and level 3 provides higher pressure variation.

(5) Low Pressure Auto Off (only CPAP mode)

Press ***"MENU"*** button to select ***[LOW P on/off]*** menu, you can view if the Low Pressure Auto Off setting is enabled and the device will be automatically turned off while detecting a large leak for 3 minutes. This setting is adjustable only by the provider, a respiratory therapist or physician.

(6) Compliance Meter

Press ***"MENU"*** button to select the ***[CM XXXX.X hr]*** menu. The compliance meter records the total therapy hours for the device. The compliance meter should be re-set only by the provider, a respiratory therapist or by a doctor.

(7) Alarm

Press ***"MENU"*** button to select the ***[Alarm on/off]*** menu, and press ***"UP"*** or ***"DOWN"*** button to set the alarm on or off. When the alarm is turned on, the audible alarm will activate with warning messages shown on the LCD display. Set alarm off to mute the audible alarm.

(8) Clock Alarm

Press ***"MENU"*** button to select the ***[Clock Alarm on/off]*** menu and press ***"UP"*** or ***"DOWN"*** button to set the clock alarm on or off. When the clock alarm is set on, the display will show the time on the left side. Press ***"UP"*** or ***"DOWN"*** button to set the time to wake you up. Once the clock alarm is activated, press the start/standby button to mute the audible alarm.

(9) Clock

Press ***"MENU"*** button to select the ***[Clock XX:XX]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the current time.

(13) Turning off the Device

Remove the power cord from the electrical outlet, and disconnect power cord from the power socket on the right side of the device.

⚠**NOTE:** Once the setting is confirmed, press the ***"MENU"*** button. Otherwise, the device will automatically go back to standby without saving the modification if no action is taken in 20 seconds.

(14) Event Indication

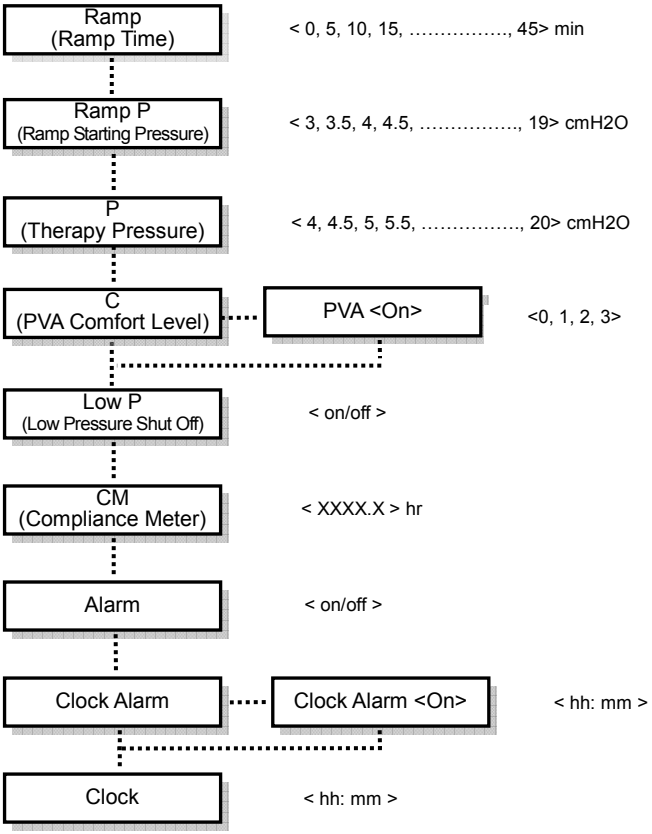
While the device is on standby mode, press ***UP"*** and ***"DOWN"*** button at the same time to see the latest one data of Apnea Index (AI), Hypopnea Index (HI) and Snoring Index (SI) on the display. Press ***"MENU"*** button to show each index in sequence. To go back to standby mode, press ***"START/STANDBY"*** button.

⚠**NOTE:**

Once the device is re-started, all the indexes will be re-calculated. The whole data of these indexes are only seen by respiratory therapists or physicians by using Easy Compliance playback software.

4.4 Flowchart of Menu settings

Enter the user's menu mode by pressing the "***MENU***" button.



In each setting, when the preferred value has been selected, press ***"MENU"*** for confirmation and press ***"MENU"*** again to enter next selection.

⚠ **NOTE:** For doctors, please refer to a separate "Doctor's Additional Instructions" manual.

4.5 Using the heated humidifier

1. Turn the control knob on the back of the device to turn on the heater and the heater on indicator
   above the knob will light up (orange light), as shown in Figure 4-1

Figure 4-1

2. Adjust the control knob to increase the humidity in the range of 1 to 6 (see diagram). 1 is minimum humidity, 6 is maximum humidity. The optimum setting is dependent on the ambient temperature and humidity of your room.

⚠ **Danger**: In order to avoid the destruction or damage to the device or even the hazard of electric shock, when the water chamber is attached, DO NOT fill water from the outlet port of the water chamber. Users must fill water no more than the maximum mark after the water chamber is removed from the device.

4.6 Using the SD card

If doctors need to review the usage data, they may ask you to use the SD card to copy data from the device, and to return the card to them. Data that is copied to the SD Card is still stored and available on the device.

1. Insert the SD Card when the device is in standby mode.
2. Data copying starts automatically when the SD Card is inserted into the slot.
3. The ***[COPY] & [Card]*** message is displayed on the LCD while data is being copied.
4. The ***[End] & [OK]*** message is displayed on the LCD when copying has finished.
5. Remove the SD Card and mail it to the clinician.
6. The SD Card should be stored in the plastic card case when not in use. The SD card does not need to be uninstalled for the device to work properly.

⚠ **CAUTION:** Do not remove the SD card until ***[End] & [OK]*** message is displayed on the LCD, or data copied to the card may be corrupted or missing.

5. Cleaning & Maintenance

5.1 Device

The device should be checked and dusted regularly (at least every 30 days). Wipe with a damp cloth and a mild detergent and keep it free from dust. If other detergent is used, choose one that will have no chemical effects on the surface of the plastic case. All parts should be air-dried thoroughly before use. Inspect the device and all circuit parts for any damage after cleaning and replace if necessary.

⚠ **WARNING:** Don't try to open this device. Repairs and internal servicing should only performed by an authorized service agent. Do not drop any object into the air tube or air outlet.

5.2 Tubing and Mask

The tubing and mask should be checked and cleaned regularly. Please refer to the cleaning instruction s that come with the accessories.

1. Disconnect the air tubing from the air outlet of the device.
2. Remove the air tubing and headgear straps from the mask.
3. Wash the mask system according to the instructions supplied with it.
4. Wash the air tubing in warm water using mild detergent. Rinse thoroughly, hang and allow to dry.
5. Before next use, assemble the mask and headgear according to the mask user instructions.
6. All items of the mask and air tubing are subject to normal wear and tear and may eventually be replaced. Replace the mask and the air tubing if they are damaged.

⚠ **CAUTION:** Do not use bleach, chlorine-, alcohol-, or aromatic-based (including all scented oils moisturizing or antibacterial soaps to clean the cushion, mask or air tubing. These solutions may cause hardening and reduce the life of the product.

⚠ **CAUTION:** Do not wash or dry the mask or air tubing at a temperature above 70°C (160°F)

⚠ **WARNING:** Do not use any cleaner containing fragrance or conditioners as they will leave a residue.

⚠ **WARNING:** The mask must not be re-used by another person. This is to avoid the risk of cross-infection.

5.3 Air Filter

For an optimum operation of the device, the air filter can be cleaned by the user at least once every two weeks or more often if this device is operated in a dusty environment. It is recommended that the filter be replaced with a new one after 6 months of use; however, depending on the air quality, the replacement time may vary.

⚠**CAUTION:** Dirty air filter may cause high operating temperatures that affect device performance. Ensure the air filter is cleaned and fitted at all times

1. Remove the dirty filter from the enclosure on the rear of the device.
2. Wash the filter in warm water with a mild detergent, and rinse with water. Allow the filter to air dry completely before reinstalling. Do not use a filter that is not completely dry. If the filter is torn, replace it.
3. Reinstall the filter.

NOTE: Please follow national requirements to dispose of the unit properly.

5.4 Water Chamber

1. Turn the heater off and allow the heater and water to cool.
2. Disconnect the flexible tubing from the water chamber. Place thumb on the top of the water chamber and lift it to separate it from the system. Open the chamber and empty the remaining water.
3. Use a mild detergent to wash all the chamber parts. Rinse all the parts with clear water and allow them to air dry.
4. All items of the chamber are subject to normal wear and tear and may eventually be replaced. Replace the chamber parts if any damage is present.

6. Troubleshooting

The table below lists troubleshooting solutions for the problems that may happen. If the problem persists, contact your equipment provider's service agent.

Problem	Possible Causes	Solutions
No display	1. The power cord is not connected to the power socket. 2. LCD failure or controlled PCB failure.	1. Ensure the power cord is connected. 2. Contact your equipment provider for repair.
Display code incorrect	LCD failure or controlled PCB failure.	Contact your equipment provider for repair.
Illuminator under LCD is not on	LED failure	Contact your equipment provider for repair.
Buttons do not work	Button failure	Contact your equipment provider for repair.
Air delivered is slow	1. During ramp time. 2. Filter is too dirty. 3. Flow generator failure.	1. Check the ramp time setting 2. Change or clean the filter regularly. 3. Contact your equipment provider for repair.
Data can not be copied to the SD card	1. SD card is full. 2. SD card is not inserted correctly. 3. Data on the SD card is corrupted.	1. Ensure the SD card has enough capacity. 2. Ensure the SD card is inserted into the slot. 3. Format the card.
Integrated humidifier power on indicator not lit up	1. Power cord not plugged into a working AC outlet. 2. Power switch is not turned on 3. PCB or indicator worn out 4. Fuse blown	1. Plug in the power cord to a working AC outlet. 2. See Set up procedure and turn the power on. 3. Contact your local agent or EU representative for service. 4. Contact your local agent or EU representative for service.
Heater on indicator not lit at all	1. Heater plate over heating 2. PCB indicator worn out	1. Contact your local agent or EU representative for service. 2. Contact your local agent or EU representative for service.
There is no air flow through the mask	1. Device is not turned on or working correctly 2. Flexible tubing is not connected right. 3. Flexible tube is blocked.	1. Check the power cord is connected properly. 2. Reconnect the flexible tubing correctly. 3. Unblock the flexible tube.

Condensation in mask or flexible tube	1. The heater plate setting is too high. 2. The operating environment or position of heated humidifier is not correct. The temperature close to mask or flexible tube is low.	1. Adjust the control knob to low temperature setting. 2. Remove any air conditioner which may nearby the heated humidifier. Or keep room temperature up near 25°C
Water Leakage	1. Wwater chamber is not properly assembled. 2. Water chamber worn out.	1. Remove the water chamber from the heated humidifier, pour out the water and reassemble the water chamber again, making sure water chamber closes securely, and fill the water till it reaches fill line and check if it still leaks or not. 2. Replace with a new water chamber.

Error / Warning Messages shown on LCD

Message type	Definition	Message in LCD
Error: Primary function can't execute.	Error for abnormal system settings	Error 001
	Error for flow generator failure	Error 002
	Error for abnormal timer setting or timer failure	Error 003
	Error for flow sensor failure	Error 004
	Error for heater failure (thermal fuse blows off)	Error 005
Warning:	Out of system memory	Warn 001
	System memory is nearly full	Warn 002
	SD card module communication failure	Warn 003
	Remove the SD card while data is being processed	Warn 004
	SD card is full	Warn 005

⚠**NOTE:** When the warning message appears, contact your doctor or equipment provider to download the memory data and reset the meter.

7. Technical Specifications

Item		Specifications
Power Supply		DC24V, 3.75A
Power Adapter		PROTEK ELECTRONICS, Model No.: PMP90F-14-B22 Input: AC 100-240VAC, 50/60Hz
Pressure Range		4 –20 cmH_2O (adjustable in 0.5 cmH_2O increments)
Ramp Time		0 – 45 minutes (adjustable in 5-minute increments)
Ramp Starting Pressure		3 cmH_2O to therapy pressure (adjustable in 0.5 cmH_2O increments)
Operating Altitude		up to 8,000 ft (2,438 m) when the pressure is set at 4-18 cmH_2O but limited to 5,000ft (1,524m) when the pressure is set at 18.5 - 20 cmH_2O
Dimensions (W x D x H)		16.5 x 19.7 x 17.6 cm
Weight		1.14 kg
Sound Level		< 29.2 dBA at 10 cmH_2O, 1 metre distance
Water Capacity		300ml
Heater Settings		1 to 6 from 40°C-70°C
Pressure Drop		0.2cmH_2O @ 60LPM
Humidity Output:		≥ 10 mgH_2O/L (Ambient temperature: 23°C ± 2°C & Relative humidity: 60% ± 15%)
Environment	Temperature	Operating: +5°C to +35°C (+41°F to +95°F) Storage: -15°C to 50°C (+5°F to +122°F) Shipping: -15°C to 70°C (+5°F to +158°F)
	Humidity	Operating: 15%RH to 95%RH non-condensing Storage: 10%RH to 90%RH non-condensing Shipping: 10%RH to 90%RH non-condensing
Classification		Class II Type BF, Applied Parts: Mask Not suitable for use in the presence of a flammable anaesthetic mixture IP21: Protected against solid foreign objects of 12.5 mm and greater; Protected against vertically falling water drops. Continuous operation.

⚠ **Note:** the manufacturer reserves the right to modify the specifications without notice.

Symbols

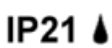
BF symbol, which indicated this product is according to the degree of protecting against electric shock for type BF equipment.

Attention, should read the instructions.

Refer to instruction manual

Attention, should read the instructions.

Class II



Protected against solid foreign objects of 12.5 mm and greater; Protected against vertically falling water drops.

Disposal of Electrical & Electronic Equipment (WEEE):
This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

Fill line

Air flow direction

Authorized representative in the European community

Manufacturer

8. Note, Caution, And Warning Statements

NOTE: Indicates information that you should pay special attention to.

CAUTION: Indicates correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

9. Servicing

The iCH series systems are intended to provide safe and reliable operation according to the instructions provided by Apex Medical. Apex Medical recommends that the iCH system be inspected and serviced by authorized technicians if there is any sign of wear or concern with device function. Otherwise, service and inspection of the devices generally should not be required during the five year design life of the device.

10. Limited Warranty

Apex Medical Corp. (hereafter 'Apex') gives the customer a limited manufacturer warranty on new original Apex products and any replacement part fitted by Apex in accordance with the warranty conditions applicable to the product in question and in accordance with the warranty periods from date of purchase as listed below. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship. To exercise your rights under this warranty, please contact your local, authorized Apex dealer.

Product	Warranty period
CPAP devices (including external power supply units)	2 years
Water chamber	6 months
Mask systems	6 months
Disposable products	None

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge(ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % UT(>95 % dip in UT)for 0,5 cycle 40 % UT(60 % dip in UT)for 5 cycles 70 % UT(30 % dip in UT)for 25 cycles <5 % UT(>95 % dip in UT)for 5 sec	<5 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT(60 % dip in UT) for 5 cycles 70 % UT(30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ 150kHz to 80MHz
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3Vrms	$d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5G MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol: ((•))

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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